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Guatemala

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

On July 19, 2009, the Government of Guatemala (GOG) published their Central American Technical ruling (CATR): 67.04.50:08. This ruling establishes the maximum level of food borne pathogens permitted in unprocessed animal products. Compliance with the microbiological criteria spelled out in the CATR will be enforced starting November 19, 2009. Procedures for enforcing these regulations have not changed and no additional microbiological certification is required. Compliance with the microbiological parameters will be determined during the registration process or during surveillance using laboratory analysis.

Section I. Food Laws:

The Division of Registration and Control of Medicines and Foods of the Ministry of Health, here after referred to as Food Control, is the main authority for food products legally imported or

manufactured in Guatemala. Government Decree # 45-79 established in 1979 the Health Code, later published and updated under Government Decree 90-97. Chapter Five of the Health Code refers to food products. Food Control, under authority of Ministerial Decree 969-99 (replaces Decree 132-85), is responsible for upholding food product norms set by the Guatemalan Ministry of Economy's Commission of Standards (COGUANOR). The Commission of Standards is governed by the Executive Advisory Committee, which is made up of representatives from the Ministry of Health, Ministry of Economy, Ministry of Labor, School of Engineers and Chambers of Agriculture, Industry and Commerce. COGUANOR will keep the mandate regarding voluntary standards, while a new commission assigned by the executive, the National Quality System, sets obligatory standards regarding processed food. Approved standards before December 17, 2005 will not be modified. The new standards commission started regulating those obligatory ones after December 17, 2005.

There are many specifications, rules, legislation and other requirements regulating food products. Decree 969-99 details various regulations related to food safety. Standards for both local and imported products are exactly the same, except for public markets and other food serving locations that require a sanitary licence but no product registration. Any producer, processor, packer, or distributor needs to operate under a sanitary licence issued by Food Control. Importers need to be legally registered and imported products need to be registered as well. Labeling is required and imported food products are marketed in Guatemala with a Spanish-language label, as the food law requires; stickers are allowed. A retailer who violates the food laws as interpreted by Food Control can be fined up to half the value of the previous day's total sales. Furthermore, there have been situations where imports have had difficulty clearing customs when the labels have not been in Spanish.

In order to receive an import permit, all imported foods of animal or vegetable origin, fresh or processed, must comply with the following requirements: phytosanitary and/or sanitary certificate, certificate of origin, commercial invoice, free sale certificate, bill of lading, and microbiological certificate for high-risk products. There are two types of certificate of origin. The Dominican Republican - Central American Free Trade Agreement (CAFTA-DR) certificate of origin fulfills customs requirements so that preferential tariffs can be applied. The other certificate of origin applies to re-exported products, especially those considered high-risk, where the original sanitary certificate is required. The Unit of Norms and Regulations (UNR) of the Ministry of Agriculture, Livestock and Food Security (MAGA) controls all of these requirements and issues the import permit. Import procedures are readily available on-line at: http://www.maga.gob.gt/maga_portal/.

Product Registration is required for all packaged food products in Guatemala. Food Control is responsible for all registrations. Regulations and registration procedures and requirements can be consulted on-line at: http://portal.mspas.gob.gt/indice_de_alimentos.html.

Food Control issues a sanitary registration number after a laboratory test has been performed on animal products. This registration number is valid for five years and in the case of animal products takes six weeks to obtain. For the other processed products, it takes approximately 7-10 days to obtain the registry number and laboratory tests will take place within routine surveillance, scheduled annually according to product category. If products do not comply with labeling standards or food safety parameters, importers will be notified as necessary. Non animal products do not require a phyto- or sanitary certificate.

It is recommended that samples be sent prior to attempting an export of high-risk (animal) products in order to obtain a sanitary registry number. Those samples must include the ingredients composition and the commercialization package, including proper labeling.

In addition to the laboratory analysis done to the product at the time of registration, for animal products, the law requires inspections at the point of entry, wholesale and retail levels for the wholesomeness of the product. Natural foods, non-processed foods, raw materials and food additives do not require registration. There is no environmental legislation that affects the importation of food products. The cost of registration and analysis of a product is about US\$215, independent of its category.

The Sample Law outlined in article 37 of Ministerial Decree 969-99 strictly prohibits the importation of samples except for the sole purpose of registering the product. However, an agreement has been reached with the United States Department of Agriculture (USDA) in which samples will be allowed to enter the country without requiring previous registration for the purpose of exhibition, special events and promotion. In order to enter these samples, the importer must provide Food Control a written request accompanied by a certificate of free sale. To avoid problems with samples, it is best not to send more than two samples of 200 grams each, per product, for registration purposes. For exhibition, special events and promotion, Food Control will allow the import of 25-50 kilograms per product, tax-free.

Microbiological - The Government of Guatemala has been demanding that a microbiological certificate accompany all unprocessed animal products. A private lab can issue this certificate, as can the quality control lab of the production plant. All microbiological certificates that are not U.S. federal documents must be stamped by a local chamber of commerce to be considered official. On July 19, 2009, the Government of Guatemala (GOG) published their Central American Technical ruling (CATR): 67.04.50:08. This ruling establishes the maximum level of food borne pathogens permitted in unprocessed animal products. The following website has further information: http://portal.mspas.gob.gt/resoluciones_comieco_alimentos.html.

Compliance with the microbiological criteria spelled out in the CATR will be enforced starting November 19, 2009. Procedures for enforcing these regulations have not changed and no additional microbiological certification is required. Compliance with the microbiological parameters will be determined during the registration process or during surveillance using laboratory analysis. Most plants in the U.S. already have systems in place to measure this as part of their Hazard and Critical Control Points (HACCP) programs. It is just a matter of sending the most recent results.

Under CAFTA-DR the U.S. meat and poultry inspection system was recognized as equivalent by the Guatemalan Ministry of Agriculture, Livestock and Food (MAGA), so that the Food Safety Inspection Service (FSIS) certificates of wholesomeness count as the microbiological, and the free sale and sanitary certificates.

Section II. Labeling Requirements:

Labeling requirements are set by COGUANOR's labeling standard #34039. It sets 40 requirements

with respect to the appearance of the label, what information should be on the label and that it must be written in Spanish. However, importers negotiated with COGUANOR and reached an agreement for a stick-on label to be used with the following information written in Spanish:

- Product definition/description
- Name of the product (This should be the official name as noted on the U.S. Certificate of free sale)
- Physical characteristics, including ingredients (This has to be a qualitative composition, which was indicated in the back of the registration form). If this information is in English, please translate literally.
- Net weight/volume
- List of ingredients (including allergens) and additives and the percentage of total for each
- Name, address and telephone number of Guatemalan distributor
- Food Control registration number (D.G.S.S.-D.R.C.A. _____-Sanitary license obtained at a Center of Sanitation); the original license has to be presented. Approximate cost for each product: Q. 1,650.00 (Q=quetzal, the national currency).
- Country of origin
- Lot production identification
- Expiration date
- If applicable "Keep Frozen" or "Form of Preparation"

Nombre del Producto: Puré para bebés; postre, sabor chocolate Ingredientes: Harina de trigo, leche entera reconstruida, azúcar, vitaminas, colorantes naturales, cocoa. 12 oz. Netas

Distribuidor: Importaciones Guatemala, S.A. Dirección: Avenida Las Estrellas, 0-01, Zona 24, Guatemala, Ciudad Teléfono: (502) 555-1212 y (502) 555-2121 D.G.S.S.-D.R.C.A. 123-456-789 Fecha de vencimiento: 31-02-02

Section III. Packaging and Container Regulations:

Imported sample-size products, under current law, must comply with existing labeling laws. Bulk-packed food products do not require labeling, unless they are to be sold at the retail level as an individual unit. Nutritional labeling in Guatemala is not required, but the Food and Drug Administration (FDA) mandatory and voluntary labeling is accepted, as long as the Spanish label includes Guatemala's mandatory information. The special shelf-life requirements specify that the use-by date be printed on the package. There have been problems with distributors importing goods with the use-by date removed or already expired. The law on use-by date can be declared as: Expiration date or best use-by date. U.S. exporters are strongly encouraged to not ship product with a nearby expiration date. This problem has led to poor relationships for more than one U.S. company. In addition, there have been situations where products came stamped with the manufactured date, and entry was rejected as the customs agent assumed the product had expired. If stamping a manufactured date is already part of a company's procedure, it is best to also add an expiration date to avoid problems.

Expiration date must be declared, at least, with date and month for products with less than three months of shelf life and month and year for products with more than three months of shelf life. Dates are to be expressed numerically, except for month that can be also expressed with letters.

Section IV. Food Additives Regulations:

COGUANOR maintains a list of additives that are permitted for use in food products. The Codex Alimentarius food additives list was used in creating the Guatemalan norm. However, all new additives accepted by the Codex are not automatically accepted by COGUANOR. COGUANOR requires a vote by the Executive Advisory Committee to add a new additive to the list. This process takes approximately six months, but it is extremely rare to have an ingredient that is permitted in Codex Alimentarius not be accepted by COGUANOR. Under the Central America Customs Union, efforts are being addressed to accept FDA additive standards for U.S. products.

Generic names of the additives plus specific names are required. Example: citric acid used as antioxidant. All functional additives must be declared according to COGUANOR norm. Sulfite is declared both as an additive as well as an allergen when it is present in concentrations of 10 mg/kg or higher.

Section V. Pesticides and Other Contaminants:

The Technical Directorate of Vegetable Health of MAGA, hereafter referred to as Vegetable Health, regulates pesticides. Vegetable Health was established by Government Decree # 43-74 and regulates all agriculturally related chemical use by authority of Ministerial decree 377-90. There are no Guatemalan standards for tolerance levels of pesticides in food products. The Government of Guatemala uses the tolerance-level standards developed by Codex Alimentarius. Vegetable Health maintains a list of pesticides that are not permitted in Guatemala. This list is based on standards set by the Environmental Protection Agency (EPA), Codex Alimentarius and the Food and Agriculture Organization (FAO), among others. All pesticides must be registered with Vegetable Health.

Section VI. Other Regulations and Requirements:

All packaged food products that are sold at the retail level need to be registered at Food Control. The requirements to register food products are as follows:

- Application for registration of food products
- Certificate of free sale
- Receipt of payment for laboratory analysis (\$215.00)
- Provide the applicable amount of samples
- Example of label design as it will appear on the product
- An authorized translator must translate all documents.
- The importer or a Guatemalan legal representative of the exporter must do the registration.

There are a number of regulations for special food groups. Decree 66-83 regulates the commercialization of substitutes for maternal milk. Beer, wine and other liquors do not need a registration number. Products labeled as "diet" must be registered as medicinal products. All products that apply for registration must be tested by the Health National Laboratory (LNS), which is the Ministry of Health's only laboratory. Product samples must be provided at time of registration. On their website, http://portal.mspas.gob.gt/indice de alimentos.html. Food Control provides a list of the microbiological parameters tested for each product during registration and later

on, during official site inspection.

Section VII. Other Specific Standards:

The Ministry of Agriculture requires that all food products of either plant or animal origin obtain an import certificate as provided in Government Decrees # 34-84 and 479-84. Decree 34-84 mandates that local manufacturing facilities of products of animal origin must be inspected by Ministry officials at the expense of the importer prior to issuance of a sanitary import certificate. However, they have not been enforcing this regulation. According to the Ministry they will require visits if ever a situation arises that represents an increased health risk, such as a disease outbreak.

The requirements to obtain a sanitary import certificate from the Technical Director of Sanitary Inspection and Control of Food Products are as follows:

- Completion of an application for Sanitary Import Certificate, one application per product
- Copy of the Articles of Incorporation
- Certification of Registration of Incorporation
- Appointment of legal representative
- Copy of Commercial License
- Sales Tax collection permit
- Import and Export License from the Bank of Guatemala
- Appointment of veterinarian as "Regente" and a note from this veterinarian accepting the
 position. This is a veterinarian who is on private contract to oversee food safety for this
 firm. The closest professional in the United States would be a Resident Veterinarian
 Inspector. He will be required to sign all import requests and is legally liable for any
 illnesses that are caused by these products.
- Determination that place of origin of product meets sanitary conditions by making an official visit. This does not apply to U.S. product.

Prior to the first importation, Ministry of Agriculture officials will inspect the warehouse where the imported product is to be stored at importer's expense. If product is to be used in a processing plant, an environmental impact study must be carried out.

Section VIII. Copyright and/or Trademark Laws:

Guatemalan Law includes the Intellectual Property Bill, which specifies that the brand or trademark must be registered in Guatemala. Trademarks and brand names should be registered at "Registro de la Propiedad Industrial" at the Ministry of Economy. The law protects known brands, so if they are already registered elsewhere, the parent company is given priority to register it in Guatemala. However, the law was not retroactive, so the person that registered it owns any brand registered prior to October 2000. All product registrations can be contested in the Guatemalan court system; however, this process can be time consuming and costly. Guatemala, as a member of the World Trade Organization (WTO), has accepted the new Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Section IX. Import Procedures:

The Guatemalan Government introduced an automated electronic customs clearance system in 2001. This system has created increased transparency in the procedure, but it has also created

problems. When the computer reads that the import product is of animal or plant origin, it will automatically require that the following documents accompany the entry application: bill of lading, phytosanitary or sanitary certificate, certificate of origin, free sale certificate, packing list, commercial invoice, microbiological certificate, and import permit. As previously mentioned, the FSIS export certificate is officially accepted for importing meat and poultry products. All documents must be originals. Below is the procedure to acquire the import certificate and the order in which to proceed.

- 1. The procedure will start at the Ministry of Agriculture. All imported products of animal or vegetable origin are inspected by the "ventanilla unica" ("single window") from the UNR. The documents required are: phytosanitary or sanitary certificate or FSIS export certificate (for meat & poultry products), commercial invoice, bill of lading, certificate of free sale, packing list, and certificate of origin (applied for re-export products). In most cases a microbiological certificate is also required. These may be copies, but in order to clear customs, the originals will be needed. An application form with the above mentioned forms must be submitted along with a fee of Q100, about US\$ 12.50, in order to receive an import permit. It is best to drop off applications before 10:00 am; if the shipment is perishable, the license will be ready for pick-up after 2:00 pm. For all regular shipments the license will be issued within 24 hours. This time frame usually holds if there are no problems with the documentation.
- 2. For processed foods and all products of animal origin, Norms and Regulations will require that the application be signed and stamped by Control de Alimentos (Food Control). This is done to verify that the product has a Sanitary Registration number. In addition, Food Control will also require a Free Sale Certificate in order to process the request. These certificates are generally issued by state health or agricultural departments, and state that the products are free for human consumption. For non-processed foods, Food Control will require a Sanitary Certificate. The application and certificates are received and issued in the offices of Food Control (5a. Avenida 13-27, Zona 9, Guatemala City), office hours from 07:30 a.m. to 3:00 p.m. from Monday to Friday.
- 3. Food Control and Norms and Regulations will authorize the import permit and the product will be inspected by Regional International Agricultural/Livestock Organization (OIRSA). This is a regional inspection entity in Central America that has been delegated the responsibility of food safety by all the Central American countries. Whether the imported product comes by air, land or sea, inspectors from OIRSA will be on site to assure that the paper work is in order. Then, inspectors perform a visual inspection of the imported products in order to authorize release from customs. In order to clear OIRSA, the original documents must be presented.
 - After the import certificate has been issued, this document is provided with all the above-mentioned documents to the customs official. The importer then pays the duties to the Superintendency of Tax Administration (SAT). The CAFTA-DR Certificate of Origin (http://dace.mineco.gob.gt/mineco/cafta/doctos_cafta/Certificado%20de%20Origen%20DR-CAFTA%20.pdf) must accompany the shipment in order to benefit from its preferences. Duty payment is done in the form of a deposit at either of the two banks that are approved, and the deposit slip becomes the proof of payment. After all this has been done, the shipment will be released. This final procedure is done at port of entry. There is still a possibility of a red or green light at the exit gate of the container. If a red light is received, there will be an additional review of both documentation and contents of container. If a

green light is received, the container is allowed to leave the yard.

The clearing process is done electronically; however, at the final stage all the documentation needs to be handed over to the customs agent (in originals) so that the shipment is released.

It is important that all quantities in all of the documents match. If not, clearing customs will be a major problem. Do not add boxes to a container once the documentation has been totaled, and always make sure that the phytosanitary or sanitary certificate's total equals the exact amount on the invoice. If there is any discrepancy, the container will be held and clearance will be extremely difficult.

U.S. exporters must always take into account that a tariff-rate quota (TRQ) system still applies to various commodities, with a 5 to 20 year phase-out period under CAFTA-DR. If you wish to look out for a particular product, you can visit

<u>www.fas.usda.gov/info/factsheets/CAFTA/overall021105a.html</u></u>. Please visit the Foreign Commerce Administration Directorate (DACE) at the Ministry of Economy web site for detailed information on TRQ administration for

Guatemala: (http://dace.mineco.gob.gt/mineco/tlc/Contingentes/conting_cafta.html). To consult and follow up on approved and assigned quotas per year, you can visit Ministry of Economy website: http://dace.mineco.gob.gt/seleccioncontingentes.php?idtratado=5.

Appendix I. Government Regulatory Agency Contacts:

Name: Licda. Gladys Arreola

Title: Director

Institution: Departamento de Regulación y Control de Alimentos

Address: 3 Calle final, 2-10 Zona 15. Valles de Vista Hermosa. Guatemala

Telefax: (502) 2369-8784 / 6

Name: Lic. Mario López

Title: Director

Institution: Unidad de Normas y Regulaciones/Ministerio de Agricultura

Address: 7 Avenida 3-67 Zona 13, Guatemala City, Guatemala

Telephone: (502) 2475-3058 Fax: (502) 2475-3058

Name: Dr. Julio Cabrera

Title: Director OIRSA-SEPA-SITC

Institution: Organismo Internacional Regional de Sanidad Agropecuaria

Address: 21 Avenida 3-12, Zona 15, Guatemala

Telephone: (502) 2369-5900 Fax: (502) 2334-0646

Name: Lic. Alejandro Cutz

Title: CAFTA-DR Administrator

Institution: Foreign Commerce Administration Direction (From the Ministry of Economy)

Address: 6 Avenida 10-43 Zona 1, Guatemala

Telephone: (502) 2412-0200

Appendix II. Other Import Specialist Contacts:

If you have any questions regarding this report or need assistance exporting to Guatemala, please contact the U.S. Agricultural Affairs Office at the following address.

Office of Agricultural Affairs, U.S. Embassy Avenida Reforma 7-01 Zona 10 Guatemala, Ciudad 01010

Tel: (502) 2332-4030 Fax: (502) 2331-8293

Email: AgGuatemala@fas.usda.gov

For further information on exporting U.S. agricultural products to Guatemala and other countries, please visit the Foreign Agriculture Service home page: www.fas.usda.gov.